

B. Status of the Claims

Claims 1-31 were filed with the original application. Claims 1-2, 5, 14-15, 17, 20-22 and 31 have been amended herein. A marked copy of the amendment is provided in Appendix A. A clean copy of the pending claims following entry of the instant amendment is provided in Appendix B. The amendments insert the accession number for a deposit of seed of variety I390186. Claims 1-31 are now pending and presented for reconsideration.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 1-31 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention.

(1) The Action rejects claims 1, 2, 5, 14, 15, 17, 20-22 and 31 for not including the ATCC accession number for a deposit of seed of variety I390186. In response, it is noted that the claims have been amended to recite the accession number. The rejection should now be moot.

(2) The Action rejects claim 2 as not being clear whether the population only consists of I390186 seed. Applicants respectfully traverse. Claim 2 is directed to a population of seed of the corn variety I390186. One of skill in the art recognizes what a population of seed is as this is the manner in which seed is sold, e.g., in a population. As with commercial seed, it is not necessary that every seed in a population be identical. The population may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I390186. For example, in commercial hybrid corn seed, a small amount of contaminating inbred seed is sometimes present. That this is the

case does not prevent one of skill in the art from understanding the meaning of a "population of seed" of a given inbred or hybrid variety. The claim is therefore fully definite under 35 U.S.C. § 112, second paragraph, and removal of the rejection is thus respectfully requested.

(3) The Action rejects claims 3 and 4 as allegedly broadening the claim from which they depend. Applicants respectfully traverse.

Claims 3 and 4 do not broaden the scope of claim 2. Claim 2 is directed to a population of seed of the corn variety I390186. Claim 3 further defines this claim by specifying "[t]he population of seed of claim 2, further defined as an essentially homogeneous population of seed." Claim 3 thus defines a further characteristic of the population of claim 2. While claim 2 is directed to a population of the corn variety I390186, it is not necessary that the population be an essentially homogeneous population of seed. The population may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I390186. Claim 3 thus further defines the scope of claim 2 and is not indefinite.

Claim 4 similarly recites "[t]he population of seed of claim 2, further defined as essentially free from hybrid seed." Once again, the population of claim 2 might contain a small amount of contaminating hybrid seed and thus not be essentially free from hybrid seed, yet still comprise a population of seed of corn variety I390186. Therefore, claim 4 further defines the claim from which it depends and is not indefinite. Removal of the rejection is thus respectfully requested.

(4) The Action rejects claim 14 for recitation of "An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I390186." Applicants respectfully traverse.

While it is true that I390186 seed can only produce I390186 plants, it is not required that a population of seed produced by growing I390186 seed contains only I390186 plants. For example, the collection of I390186 seed used to plant the population of I390186 plants may contain small amounts of other seed. Alternatively, other types of plants may grow within a population of plants that are grown, whether from I390186 seed or another type of seed, that were not necessarily intended to be grown, including weeds. As such, "essentially homogeneous" further defines the scope of the claim and the term as it is used is not indefinite.

In view of the foregoing, removal of the rejections under 35 U.S.C. §112, second paragraph is respectfully requested.

D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 2-4, 14 and 24-31 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. Applicants respectfully traverse.

With respect to populations of seed of corn variety I390186, the Action suggests that, in populations of seed comprising less than 100% I390186 seed, the identity of the remaining seed is unknown. In response, Applicants first note that the Patent Office has issued more than 75 patents including claims to populations of corn seed of a given

variety. Thus, the impetus for the instant rejection is not understood. It is further noted that the identity of any other seed included in a population of seed of variety I390186 is irrelevant. The fact that claimed populations of seed of variety I390186 may not be completely purified, and thus may comprise unspecified contaminant seed, does not take the claim out of compliance with the written description requirement.

Under the reasoning in the Action, any open language in a claim would be impermissible because it is unknown what other components might be contained in a given composition. For example, a claim to a composition "comprising ingredient A," would lack written description because there is an infinite scope of other possible ingredients that could be added to the composition. Here, the claims are directed to populations of seed of variety I390186 that may or may not be completely purified. As set forth above, however, this is irrelevant to written description as seed of variety I390186 has been fully described and the identity of any contaminant seed is irrelevant to the scope of the claim. What is claimed is a population of seed of variety I390186 that need not necessarily be absolutely purified.

Applicants have also fully described the other subject matter cited in the Action in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. In particular, the specification provides a description of sufficient structural characteristics of hybrid plants having inbred corn plant I390186 as one parent to satisfy the written description requirement. For example, the specification provides a detailed description of hybrid 0004411, which was produced with I390186 as one inbred parent. Table 5 of the specification gives the morphological traits of 0004411. Further, the SSR marker profile and isozyme marker profile for hybrid 0004411 are given in Tables 8 and

9, respectively. This information, combined with the descriptions of the genetic and morphological characteristics of I390186 in the specification, as well as the fact that any hybrid derived from I390186 will contain half of its genes from I390186, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant I390186 in compliance with the written description requirement.

The specification further provides an SSR genetic marker profile of I390186 in Table 6. Because corn plant I390186 is an inbred corn plant, all hybrid plants having I390186 as a parent will contain these SSR genetic markers and thus will be genetically distinct and identifiable from any other corn plant on this basis. That is, because I390186 is an inbred corn plant, all hybrid corn plants derived therefrom will inherit half of the genetic material of corn plant I390186.

The Federal Circuit has noted that such shared identifiable structural features possessed by members of a genus is important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I390186 as one parent share the structural feature of having the genetic complement of I390186. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The Action also rejects claims to single locus conversions of corn plant I390186 on the basis that I390186 may allegedly be altered in any of its traits and that the specification does not describe single locus conversions and transgenes that have the ability to alter any given maize plant trait. In response, it is first noted that the relevant claims are directed to corn plant I390186 which further comprises a single locus conversion. Such a "single locus converted (conversion) plant" is defined at page 23 of the specification as follows:

[p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". Applicants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I390186 by way of the descriptions of I390186. To hold otherwise would be to limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

The rejection also ignores the substantial description in the specification supporting single locus conversions of I390186. For example, at pages 29-31, the methodology for creating single locus converted plants is described. At pages 30-33, numerous single locus traits for creation of single locus converted plants are described, such as those conferring male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. Many of these traits are also described in PCT Application WO 95/06128, the disclosure of which is incorporated by reference in the current specification. The specification also provides examples of genes conferring male sterility, including those disclosed in U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No. 5,625,132, and U.S. Patent No. 4,727,219, the disclosures of which were also incorporated by reference in the current application.

At pages 29-31, detailed methodology and compositions are described for introducing male sterility into inbred corn plant I390186, including the use of one or more male-fertility restorer genes. Examples of such male-sterility genes and corresponding restorers are given by way of U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, each of the disclosures of which were incorporated by reference in the current application. Methods for selection of dominant single locus traits are also described at page 32, for example, such as a herbicide resistance trait.

Further described at page 32 of the specification is the preparation of transgenic single locus conversions, including those created by electroporation (U.S. Patent No. 5,384,253), electrotransformation (U.S. Patent No. 5,371,003), microprojectile

bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765).

The use of a single locus trait conferring resistance to the herbicide glyphosate is described at page 32-34, including a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060), as well as a mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103). Methods for the use of these single locus conversions are also described. Further described, are numerous other single locus traits for preparation of single locus conversions, including a selectable marker gene encoding phosphinothricin acetyl transferase (PPT) (*e.g.*, a bar gene), a gene encoding an endotoxin from *Bacillus thuringiensis* (Bt), and the waxy characteristic, each of which are well known to those of skill in the art. Still further, the specification describes, at pages 34-35, an example of the origin and breeding history of an exemplary single locus converted plant, including all steps necessary for the preparation of the single locus converted plant.

The detailed description of single locus traits and of corn plant I390186 is more than adequate to provide a written description of single locus conversions of corn plant I390186. The specification itself defines a single locus converted plant comprises essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, I390186. While Applicants have not described every possible single locus conversion that could be introduced into corn plant I390186, this is

not required under the written description requirement. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

The Action also rejects claim 31, which is drawn to a method of producing an inbred corn plant derived from the corn variety I390186 by use of plant breeding steps. The instant written description rejection is not understood, however, as all of the method steps are fully recited. No allegation has been made that any particular essential step has been omitted or has not been described. Written description must be analyzed with respect to the *claimed invention*. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Here, all of the steps of the method are recited described in the claim and, therefore, are fully supported by a written description.

In view of the foregoing Applicants respectfully request the removal of the rejection.

E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

(1) The Action rejects claims 1-31 under 35 U.S.C. §112, first paragraph, for lack of a seed deposit.

In response, Applicant notes that a deposit of 2,500 seeds of the variety I390186 was made with the ATCC. The deposit was made in accordance with the terms and provisions of 37 C.F.R. §1.808 relating to deposits of microorganisms. The deposit was made for a term of at least thirty years or at least five years after the most recent request for furnishing of a sample of the deposit is received by the depository or for the effective life of the patent, whichever is longer. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 is attached hereto under **Appendix C**.

The rejected claims have each been amended, either directly or by way of dependency upon an amended claim, to recite the accession number for those seeds of the inbred corn plant I390186 which have been deposited with the ATCC. The claim amendments do not narrow the claims and accordingly Applicant does not intend to disclaim any subject matter through the amendments. The specification has also been amended to include the accession number of the deposit and the date of deposit.

In light of the foregoing, Applicant respectfully requests removal of the rejection under 35 U.S.C. §112, first paragraph.

(2) The Action rejects claims 27, 29 and 30 under 35 U.S.C. §112, first paragraph as allegedly not enabled. Applicants respectfully traverse.

The rejected claims are directed to corn plants of variety I390186 comprising a single locus conversion. In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No allegation has been made that the references refer to corn plants. The relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

The Action disregards Applicants example of a conversion that has been made with a proprietary corn variety by stating that information has been left out, such as the number of crosses that were performed at each step. This is incorrect. The breeding history of the conversion that was made is given. In the breeding history, seven backcrosses are described. No steps are left out and no basis has been provided to

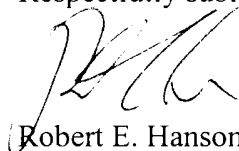
demonstrate why this example does not demonstrate enablement for the instant variety. In view of Applicants example, the detailed teaching in the specification and the failure to provide any basis to doubt the enablement of the claims, removal of the rejection is respectfully requested.

F. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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